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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,933	01/07/2004	Peter M. Bonutti	2500DV2CN2DV3CN8	5806

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Patent Counsel  
United States Surgical, a division of  
TYCO HEALTHCARE GROUP LP  
150 Glover Avenue  
Norwalk, CT 06856

EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/752,933

Applicant(s)

BONUTTI, PETER M.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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Claims 1 and 4-12 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Froning (3,875,595). Froning discloses cannula 31 and a retractor including shaft 47, 48 and inflatable bladder 46 which is inherently capable of retracting opposed surfaces of a bone joint since the inflation of the bladder would inherently apply an outward pressure against the opposed surfaces to retract them. Alternatively, it would have been obvious that inflatable bladder 46 is capable of retracting opposed surfaces of a bone joint for the reasons set forth above. As to claim 4, bladder 46 is eccentrically mounted on shaft 47 as seen in figure 6. As to claim 5, any stretching of the bladder 46 will be finished when it is fully inflated. As to claim 8, portion 48 of the shaft is rigid. As to claim 10, Froning discloses a viewing scope (the cystoscope described in the abstract). As to claim 11, Froning discloses an interventional instrument (e.g. the instrument described in col. 2, lines 38-41).

Claims 1 and 4-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheldon (3,417,745). Sheldon discloses cannula 5 and a retractor (figure 4) including shaft (the combination of parts 2 and inflation channel 56) and inflatable bladder (57 or 57a) which is inherently capable of retracting opposed surfaces

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of a bone joint since the inflation of the bladder would inherently apply an outward pressure against the opposed surfaces to retract them. The inflatable members 57 and 57a are inherently capable of separating opposed surfaces of a bone joint since they provide outward force when they inflate, particularly since 1) they are made of Mylar which is very strong and does not stretch when inflated and 2) they are filled with liquid (the fluid in the phrase "fluid or gas" referred to in col. 8, line 68) which is substantially non-compressible. Thus, the inflatable members 57 and 57a, if located between opposed surfaces of a bone joint during inflation, would inherently provide an outward force to separate the portions of the joint. Alternatively, it would have been obvious that inflatable bladder 46 is capable of retracting opposed surfaces of a bone joint for the reasons set forth above. As to claim 9, portion 56 of the shaft is flexible.

Applicant's arguments filed June 7, 2006 have been fully considered but they are not persuasive. The Frong bladder 46 is inherently capable of separating adjacent portions of bone tissue upon inflation since it provides a relatively large outward force when it inflates, and since only a relatively small force is required to separate opposed surfaces of a bone

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joint. The Froning bladder 46 provides a relatively large outward force when it inflates for the following reason:

Inflation of the Froning bladder 46 would inherently apply a relatively large outward pressure against the opposed surfaces to retract them since the insertion of the inflation water under pressure into the bladder (col. 3, lines 17-20) would necessarily force the walls of the bladder outwardly to expand it and any surrounding tissue, particularly since water is a substantially incompressible material.

Only a relatively small force is required to separate opposed surfaces of portions of bone joint to create a working space for the following reasons:

First, the type of bone joint is not defined in the claims. Some bones are easily separated with little force. For example, when many people pull on a finger or thumb (with very little force) and release it they feel the finger bone slightly separate from the adjacent bone in the palm and impact each other when the finger is released. Note that the amount of separation or the amount of working space created is not claimed. Thus, bladder 46 of Froning, if placed between these bones in a hand and inflated, would inherently separate them.

Second, the conditions of the connective tissue surrounding the bones are not defined in the claims. For example, the

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adjacent bones of a patient with completely torn ligaments would be very easily separated with little or substantially no force since no connective tissue holds the bones together. Thus, bladder 46 of Froning, if placed between these bones and inflated, would inherently separate them.

The allegation that Sheldon fails to disclose a cannula having a passage that receives the shaft to deploy the bladder at a target site in tissue is unfounded. Sheldon clearly discloses a cannula (the needle 5) having a passage that receives the shaft (the spinescope 7) noting col. 3, lines 10-13 and figure 1. In any event, Sheldon, in col. 9, lines 59-70, indicates that the spinescope with a bladder is inserted into a smaller needle to enter the extra-dural space, indicating that the smaller needle has an open distal end to permit such entry. Further, contrary to appellant's remarks, Sheldon, in col. 3, lines 6-10 indicates that the tip 5b consists only of the bottom wall 5c and side walls 5d and has no closing wall above bottom wall 5c. Thus, the open distal end above the bottom wall 5c is inherently capable of enabling the passage of the shaft 7 therethrough, particularly when the halves 6 and 6a are spread apart as described in col. 3, lines 28-33.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

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mht  
8/4/06

A handwritten signature in black ink, appearing to read 'Michael Thaler', written in a cursive style.

MICHAEL THALER  
PRIMARY EXAMINER  
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